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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,832	12/20/2001	France Couture	BIOVAC-15	1503

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/022,832	COUTURE ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 1944*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 34-46* is/are pending in the application.

4a) Of the above claim(s) *1-16, 19, 20, 22-31 and 35-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18,21,34,45 and 46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 December 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *32502 & 6603*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Sequence report - One page*.

DETAILED ACTION

Preliminary Amendments

1) Acknowledgment is made of Applicants' preliminary amendments filed 12/20/01, 03/07/02, and 03/25/02. With at least one of these, Applicants have amended the specification.

Election

2) Acknowledgment is made of Applicants' election filed 11/08/04, with traverse, of invention II, claims 17, 18, 21, 34, 45 and 46, drawn to the BVH-CPN-1 polypeptide of SEQ ID NO: 2, fragments, or analogs thereof; a composition and a kit comprising the same, in response to the restriction requirement mailed 09/29/04. Applicants' traversal is on the grounds that all the claims in the application that involve BVH-CPN-1 involve related subject matter and therefore a search would comprise overlapping subject matter. Applicants submit that such a search would not be burdensome. Applicants cite MPEP 803 and state that if search and examination of an entire application can be made without a serious burden, the Examiner must examine it on the merits even though it includes claims to independent or distinct invention.

Applicants' arguments have been carefully considered, but are not persuasive. Contrary to Applicants' argument, all the claims that involve BVH-CPN-1 do not involve related subject matter. As set forth in the restriction requirement mailed 09/29/04, the products claimed in different inventions have a structure, or amino acid or nucleotide composition that is significantly distinct from the other. A structural search for one product is not coextensive with the other due to the structural diversity of the sequences, and therefore a structural search for one product would not yield prior art patents or references on the other product(s). For these reasons, the restriction requirement set forth in the instant application is proper and is hereby made FINAL.

Status of Claims

3) Claims 32 and 33 have been canceled via the amendment filed 03/07/02.

Claims 21, 30 and 31 have been amended via the amendment filed 03/07/02.

New claims 34-66 have been added via the amendment filed 03/07/02.

Claims 1-31 and 34-46 are pending.

Claims 1-16, 19, 20, 22-31 and 35-44 have been withdrawn from consideration as being directed to a non-elected invention. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 17, 18, 21, 34, 45 and 46 are under examination. A First Action on the Merits is

issued for these claims.

Sequence Listing

4) The raw sequence listing submitted in this application has been entered on 04/04/2002.

Information Disclosure Statements

5) Acknowledgment is made of Applicant's Information Disclosure Statements filed 3/25/02 and 06/06/03. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Priority

6) The instant application claims priority to the provisional application, 60/256,941, filed 12/21/2000.

Specification - Informalities

7) The specification of the instant application is objected to for the following reasons:

(a) The use of the trademark in the instant specification has been noted. For example, 'QuilA' in the last paragraph on page 32; and 'McVector' in the last paragraph on page 33. The recitations should be capitalized wherever they appear or be accompanied by the generic terminology. See M.P.E.P 608.01(V) and Appendix I. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

(b) On page 40, line 32 and in the last paragraph of page 37, the address of the American Type Culture Collection is incorrect. Effective 23 March 1998, ATCC has a new address: 10801 University Boulevard, Manassas, VA 20110-2209. Amendments to the specification are suggested to reflect this. It is suggested that Applicants examine the whole specification to make similar correction to the address, wherever it appears.

(c) The nucleotide sequence recited in lines 6 and 7 of page 38 of the specification contains more than ten nucleotide bases, yet is not identified by a SEQ ID number as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification, which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note

that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

Rejection(s) under 35 U.S.C § 112, First Paragraph

8) Claims 17, 18, 21, 34, 45 and 46 are rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. See *Interim Guidelines on Written Description* published 15 June 1998 in the *Federal Register*, volume 63, number 114, pages 32639-32645. This is a written description rejection.

The claimed polypeptide having 'at least 95%' or 'at least 70%' identity (i.e., a polypeptide variant) to a polypeptide having the amino acid sequence of SEQ ID NO: 2, or 'fragments' or 'analogs' thereof; 'fragments' or 'analogs' of a polypeptide capable of generating antibodies having binding specificity for a polypeptide having the amino acid sequence of SEQ ID NO: 2; and 'fragments' or 'analogs' of an epitope-bearing portion of a polypeptide having the amino acid sequence of SEQ ID NO: 2 are not associated with any function in the claims. However, the specification discloses diagnostic, prophylactic and therapeutic applications for the claimed polypeptide variant and fragments or analogs thereof. Therefore, the products claimed in the instant claims do not exist independent of their ability to induce a prophylactic, therapeutic or protective immune response in an animal or a human against infection by *Chlamydia*. However, the instant specification fails to teach a single such polypeptide variant, 'fragment' or 'analog' thereof of the polypeptide or polypeptide variant, or an epitope of the polypeptide concurrently having the ability to induce a prophylactic, therapeutic or protective immune response in an animal or human host against infection by any strain of *Chlamydia*. Diagnostic or vaccine applications minimally require an ability to elicit a specific immune response or bind specifically to an antibody. The precise structure or relevant identifying characteristics of each polypeptide variant and an 'analog' or 'fragment' of a polypeptide variant or polypeptide epitope as recited, having the functional activity can only be determined empirically by actually making every variant, fragment or analog, and

testing each varied or truncated polypeptide molecule to determine whether it has the particularly disclosed prophylactic, therapeutic or protective activity. The *Written Description Guidelines* state:

> There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between the structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function.

A mere statement that the invention includes a polypeptide variant, analogs or fragments as recited is insufficient to meet the adequate written description requirement of the claimed invention. The polypeptide of SEQ ID NO: 2 has specific biologic or immunogenic properties dictated by its structure and the corresponding structure of the structural gene sequence which encodes it. A convincing structure-function relationship has to exist between the structure of the gene sequence, the structure of the polypeptide encoded, and the function of the encoded polypeptide. The function cannot be predicted from the modification of the structure of the polypeptide and in the instant case, the claimed polypeptide variant, fragment or analog. Applicants have not shown that variation or modification of a reference polypeptide sequence as claimed would automatically predict the production of a polypeptide variant, analog or fragment having the functional activity of the native polypeptide, i.e., the ability to induce a protective immune response in a mammal against *Chlamydia pneumoniae* infection. The specification fails to teach the structure or relevant identifying characteristics of a representative number of species of polypeptide variants, analogs and fragments, sufficient to allow one skilled in the art to determine that the inventors had possession of the invention as claimed. With the exception of a polypeptide of SEQ ID NO: 2, a skilled artisan cannot envision the detailed chemical structure of all the polypeptide variant, fragment or analog species encompassed by the recited molecule. Regardless of the complexity or simplicity of the method of isolation, conception cannot be achieved until reduction to practice has occurred. Adequate written description requires more than a mere statement that its is a part of the invention and a reference to a potential method of isolating it. The polypeptide variant, analog or fragment having the function itself is required. See *Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993)* and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991) clearly states that 'Appellant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991) at 1117.

The specification does not 'clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed'. *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111 (Fed. Cir. 1991) at 1116.

9) Claims 17, 18, 21, 34, 45 and 46 are rejected under 35 U.S.C § 112, first paragraph, because the specification, while being enabling for the isolated BVH-CPN1 polypeptide of *Chlamydia pneumoniae* comprising the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for a polypeptide that has at least 95% or 70% identity to the polypeptide having the amino acid sequence of SEQ ID NO: 2 (i.e., polypeptide variant) and fragments or analogs thereof as claimed.

The instant claims are evaluated based on the *Wands* analysis. Many of the factors regarding undue experimentation have been summarized in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Circ. 1988) as follows:

- The quantity of experimentation necessary (time and expense);
- The amount of direction or guidance presented;
- The presence or absence of working examples of the invention;
- The nature of the invention;
- The state of the art;
- The relative skill of those in the art;
- The predictability or unpredictability of the art; and
- The breadth of the claims.

In the instant case, the nature of the invention is related to a polypeptide of SEQ ID NO: 2, its 95% or 70% identical sequence variant, and analogs or fragments thereof; and fragments or analogs of an epitope-bearing portion of a polypeptide of SEQ ID NO: 2. The purpose of the invention is to use the claimed products for diagnostic, therapeutic and prophylactic purposes in animals and humans. This means that the polypeptide variant, analogs or fragments thereof as claimed, are required to induce a prophylactic, therapeutic or protective immune response against infections caused by homologous *C. pneumoniae* or heterologous strains of *Chlamydia*. Example 4 describes the ability of the BVH-CPN1 polypeptide to reduce the chlamydial lung titer in mice immunized with the polypeptide. However, there is absolutely no evidence within the instant specification that a variant of SEQ ID NO: 2, analogs or fragments thereof as explained above were made and were able to induce a prophylactic, therapeutic or protective immune response against infection by *C. pneumoniae* or any strain of *Chlamydia*, or were able to bind specifically with an antibody to *C. pneumoniae* or any strain of *Chlamydia* such that they could be used for diagnostic

purposes. It is unlikely that the claimed polypeptide variant with 5-30% dissimilarity to the polypeptide of SEQ ID NO: 2, analogs or fragments thereof, would remain *C. pneumoniae*-specific or *Chlamydia*-specific. With regard to the 95% or 70% identical polypeptide and analogs and fragments thereof, the specification provides no guidance as to which amino acid residues must be retained in the polypeptide variant, analogs or fragments thereof, or which may be varied without causing any detrimental effect to the claimed polypeptide that is meant for diagnostic use, or for inducing a therapeutic, prophylactic or protective immune response in an animal or human against *C. pneumoniae* or *Chlamydia*. There is no information in the instant specification with regard to which amino acid variations, i.e., insertions, deletions, additions and substitutions, in the polypeptide would result in a variant or analog polypeptide, analogs or fragments thereof that would retain the functional integrity or biological/immunogenic competence of the native polypeptide, without rendering it non-functional. This is important because the art reflects unpredictability as to which amino acid residues in a specific polypeptide can be varied, i.e., replaced or added, without adversely affecting the functional properties of the specific polypeptide. While it is known in the art that variation is possible in a given polypeptide or protein, the exact position within its sequence where replacements or variations can be made, with a reasonable expectation of success of retaining the molecule's functional integrity, is not certain. A random replacement affecting the protective epitopic positions that are critical, for example, to the three-dimensional conformational structure and specific binding property of the molecule, would result in a polypeptide that may be non-functional (i.e., non-immunogenic or non-antigenic) or not optimally immunogenic as a vaccine candidate, or not optimally antigenic as a diagnostic reagent, because such positions tolerate no or little-modifications. For instance, Houghten *et al.* (New Approaches to Immunization, *Vaccines86*, Cold Spring Harbor Laboratory, p. 21-25, 1986) teach the criticality of individual amino acid residues and their positions in peptide antigen-antibody interactions. Houghten *et al.* state (see page 24):

> One could expect point mutations in the protein antigen to cause varying degrees of loss of protection, depending on the relative importance of the binding interaction of the altered residue. A protein having multiple antigenic sites, multiple point mutations, or accumulated point mutations at key residues could create a new antigen that is precipitously or progressively unrecognizable by any of the antibodies in the polyclonal pool.

Thus, the art reflects that variations in critical residues at specific positions of a polypeptide could result in a molecule which may induce an antibody that may not recognize or bind to the native microbial molecule. In the instant case, this is important because one of the purposes of the instant

invention is to produce a chlamydial polypeptide in its biologically active, immunogenic and/or protective form for inducing a prophylactic or therapeutic immune response. The instant disclosure lacks guidance on the precise position(s), nature and extent of replacements or variations that can be made in the claimed polypeptide in order to produce a variant or a analog, and with regard to whether it would serve as an immunogen capable of conferring immunity to chlamydial infections in an animal or human host, or as an antigen capable of binding specifically to an antibody to the polypeptide or to homologous or heterologous *Chlamydia*. There is no predictability that a polypeptide having as much as at least 30% or 5% dissimilarity with SEQ ID NO: 2 would even remain chlamydia-specific let alone optimally prophylactic or therapeutic, antigenic, or immunogenic. Therefore, undue experimentation would have been required to reproducibly practice the full scope of the invention as claimed currently, due to the lack of adequate and specific guidance, the lack of evidentiary support in the specification enabling the claimed polypeptide variant, analogs or fragments thereof, as prophylactic or therapeutic agents, or diagnostic reagents, the nature of the invention, the state of the prior art, the quantity of experimentation necessary and the art-demonstrated unpredictability in determining variations that are acceptable. *Ex parte Foreman*, 230 USPQ 546, 547 (Bd. Pat. Appls. and Interf. 1986). The production and the use of a chlamydial polypeptide variant and fragments or analogs thereof which are capable of inducing a therapeutic or prophylactic immune response against infection by homologous or heterologous chalmydial strains in an animal or human host is well outside the realm of routine experimentation. The claims are viewed as not meeting the scope of enablement provisions of 35 U.S.C § 112, first paragraph.

Rejection(s) under 35 U.S.C § 112, Second Paragraph

10) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

11) Claims 17, 18, 21, 34, 45 and 46 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claims 17 and 18 are vague and indefinite in the limitation 'polypeptide having an amino acid sequence' (see parts (a) and (b) of the claim) as opposed to the definite limitation -- polypeptide having the amino acid sequence--.

(b) Claims 17 and 18 are vague and indefinite in the limitation 'a sequence' (see parts (c), (d) and (e) of the claim) as opposed to the definite limitation --the amino acid sequence--. The claims fail to distinctly recite that the sequence represents --the amino acid sequence--.

(c) Claims 17 and 18 are vague and indefinite in the limitations: 'fragments' and 'analogs', because it is unclear what is encompassed in these limitations. What constitutes a fragment or an analog, and how much of the polypeptide's original structure has to be retained such that the resulting products can be considered as 'fragments' or 'analogs' is not clear. The metes and bounds of the structure encompassed in the limitations 'fragments' and 'analogs' are indeterminate.

(d) Claims 17 and 18 are vague and indefinite in the limitation '% identity' because it is unclear what is encompassed in this limitation. Does this represent functional identity, biological identity, structural or sequence identity?

(e) Claim 21 lacks proper antecedent basis in the limitation: 'a polypeptide according to ..... claims 17....'. For proper antecedence, it is suggested that Applicants replace the limitation with --the polypeptide according to ..... claims 17--.

(f) Claim 24 lacks proper antecedent basis in the limitation: 'a polypeptide according to claim 18'. For proper antecedence, it is suggested that Applicants replace the limitation with --the polypeptide according to claim 18--.

(g) Claims 45 and 46 lack proper antecedent basis in the limitation: 'a polypeptide according to claim ...'. For proper antecedence, it is suggested that Applicants replace the limitation with --the polypeptide according to claim ...--.

(h) In claims 45 and 46, for clarity and for the purpose of distinctly claiming the subject matter, it is suggested that Applicants replace the limitation 'said infection' with --said bacterial infection--.

(i) Claims 21, 34, 45 and 46, which depend directly or indirectly from claim 17 or 18, are also rejected as being indefinite because of the indefiniteness or vagueness identified above in the base claim.

Rejection(s) under 35 U.S.C § 102

12) The following is a quotation of the appropriate paragraph(s) of 35 U.S.C. § 102 that form the basis for the rejection(s) under this section made in this Office action:

> A person shall be entitled to a patent unless –
> **(b)** the invention was patented or described in a printed publication in this or a foreign country or in public use

or on sale in this country, more than one year prior to the date of application for patent in the United States.

13) Claims 17, 18, 21, 34, 45 and 46 are rejected under 35 U.S.C § 102(b) as being anticipated by Griffais *et al.* (WO 99/27105 – Applicants' IDS).

Griffais *et al.* disclosed an isolated or purified chlamydial polypeptide having an amino acid sequence that shows 100% sequence identity with the instantly claimed polypeptide of SEQ ID NO: 2, biologically active fragments thereof, and a homologous or modified polypeptides thereof, i.e. analogs, having amino acid substitutions without the biological activities being modified. See the attached sequence search report; abstract; Table 3; paragraph bridging pages 13 and 14; lines 1-11 of page 14; pages 15-17 and 20-25; and pages 33, 37, 39 and 44. The prior art polypeptide is capable of eliciting an immune response directed against *Chlamydia pneumoniae*, and is capable of being recognized by an antibody specific to the polypeptide (see page 17). The modified polypeptide is modified or truncated by deletion of the N-terminal or C-terminal end (see page 18). The polypeptide is advantageously used in *in vitro* and *in vivo* methods for the detection and identification *Chlamydia pneumoniae* in a biological sample (see paragraph bridging pages 58 and 59; page 59). A kit comprising the polypeptide for the detection and/or the identification of bacteria belonging to the species of *Chlamydia pneumoniae* (see paragraph bridging pages 59 and 60; paragraph bridging pages 60 and 61; pages 65 and 66) is taught. A pharmaceutical composition or a vaccine comprising a pharmaceutically acceptable carrier, the polypeptide and an adjuvant such as aluminum hydroxide for immunizing an animal is taught (see paragraph bridging pages 60 and 61; lines 25-37 on page 68; lines 1- 12 of page 69; and pages 70, 71 and 73).

Claims 17, 18, 21, 34, 45 and 46 are anticipated by Griffais *et al.*

Objection(s)

14) Claims 17, 18, 21, 34, 45 and 46 are objected to for the following reasons:

(a) Claims 17, 18 and those dependent therefrom are objected to for including non-elected subject matter.

(b) Claim 21 is objected to for depending from a non-elected claim, i.e., claim 19 or 20.

Relevant Prior Art

15) The prior art made of record and not relied upon is considered pertinent to Applicants' disclosure.

- Griffais *et al.* (US 6,559,294, filed 11/23/1998) taught an isolated chlamydial

polypeptide that has 100% sequence identity with the instantly claimed polypeptide of SEQ ID NO: 2 and a composition comprising the same (see entire document).

Remarks

16) Claims 17, 18, 21, 34, 45 and 46 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

January, 2005

S. DEVI, PH.D.
PRIMARY EXAMINER

SEQ ID NO. 2

```
RESULT 1
AAY35281
ID   AAY35281 standard; protein; 258 AA.
XX
AC   AAY35281;
XX
DT   17-OCT-2003  (revised)
DT   13-SEP-1999  (first entry)
XX
DE   Chlamydia pneumoniae transmembrane protein sequence.
XX
KW   Respiratory disease; pneumonia; bronchitis; heart disease; sarcoidosis;
KW   sinusitis; purulent otitis media; erythema nodosum; pharyngitis; vaccine;
KW   neutralising epitope.
XX
OS   Chlamydophila pneumoniae.
XX
PN   WO9927105-A2.
XX
PD   03-JUN-1999.
XX
PF   20-NOV-1998;   98WO-IB001890.
XX
PR   21-NOV-1997;   97FR-00014673.
PR   04-NOV-1998;   98US-0107078P.
XX
PA   (GEST ) GENSET.
XX
PI   Griffais R;
XX
DR   WPI; 1999-357842/30.
XX
PT   Genome sequence of Chlamydia pneumoniae.
XX
PS   Page 1103-1104; Disclosure; 1912pp; English.
XX
CC   AAY34584-Y35879 represent the proteins encoded by all the open reading
CC   frames in the complete genome (see AAX91990) of Chlamydia pneumoniae. C.
CC   pneumoniae causes respiratory disease such as pneumonia and bronchitis
CC   and is thought to be a contributing factor in heart disease, sarcoidosis,
CC   sinusitis, purulent otitis media, erythema nodosum or pharyngitis. The
CC   polypeptides encoded by the open reading frames of the C. pneumoniae
CC   genome (see AAY34584-Y35879) can be used in immunogenic compositions as
CC   vaccines. Vectors containing C. pneumoniae nucleotides sequences can also
CC   be used as immunogenic compositions, especially where the vector directs
CC   the expression of a neutralising epitope of C. pneumoniae. (Updated on 17
CC   -OCT-2003 to standardise OS field)
XX
SQ   Sequence 258 AA;

  Query Match          100.0%;  Score 1299;  DB 2;  Length 258;
  Best Local Similarity  100.0%;  Pred. No. 5.2e-118;
  Matches  258;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 MNRRWNLVLATVALALSVASCDVRSKDKDKDQGSLVEYKDNKDTNDIELSDNQKLSRTFG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 MNRRWNLVLATVALALSVASCDVRSKDKDKDQGSLVEYKDNKDTNDIELSDNQKLSRTFG 60

Qy         61 HLLARQLRKSEDMFFDIAEVAKGLQAELVCKSAPLTETEYEEKMAEVQKLVFEKKSKENL 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 HLLARQLRKSEDMFFDIAEVAKGLQAELVCKSAPLTETEYEEKMAEVQKLVFEKKSKENL 120

Qy        121 SLAEKFLKENSKNAGVVEVQPSKLQYKIIKEGAGKAISGKPSALLHYKGSFINGQVFSSS 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 SLAEKFLKENSKNAGVVEVQPSKLQYKIIKEGAGKAISGKPSALLHYKGSFINGQVFSSS 180

Qy        181 EGNNEPILLPLGQTIPGFALGMQGMKEGETRVLYIHPDLAYGTAGQLPPNSLLIFEINLI 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 EGNNEPILLPLGQTIPGFALGMQGMKEGETRVLYIHPDLAYGTAGQLPPNSLLIFEINLI 240

Qy        241 QASADEVAAVPQEGNQGE 258
              ||||||||||||||||||
Db        241 QASADEVAAVPQEGNQGE 258
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